

## **REMARKS / ARGUMENTS**

### ***Remaining Claims***

Eight (8) claims (Claims 1 - 3 and 5 - 9) remain pending in this application through this Amendment. Claim 4 has been deleted; Claims 1 - 3 have been amended herein; and Claims 10 - 14 have been removed from consideration as drawn to a nonelected invention. Furthermore, Applicants affirm the provisional election of the crosslinker of Example 1a made by Applicants' attorney by phone on March 13, 2003.

Attached hereto is a marked-up version of the changes made to the claims and the specification by the present amendment. The attached page is captioned "Version With Marking To Show Changes Made."

### ***Rejection of Claims 1 - 9 under 35 USC §112, first paragraph***

Claims 1 - 9 stand rejected under 35 USC §112, first paragraph, because the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have amended Claim 1 to specify that it is the functional groups of the chain transfer agent comprised in the resulting copolymer that are reacted. While Applicants believe that this amendment clarifies the invention and addresses the Examiner's rejection, if the Examiner disagrees, Applicants would appreciate Examiner's suggestions on proper language in this regard. Applicants, therefore, respectfully request that this rejection be withdrawn.

### ***Rejection of Claims 1-9 under 35 USC §112, second paragraph***

Claims 1-9 stand rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Applicants have amended Claim 1 to change "is obtainable" to "is obtained" as kindly suggested by the Examiner.

Claim 1 has been amended to more clearly define the term "hydrophilic" by incorporating language from Page 2 of the specification. Applicants further submit that one of ordinary skill in the art would understand the metes and bounds of this definition as used in the biomedical device industry.

Lastly, Applicants have amended Claims 2 and 3 to include proper indentation, punctuation, and Markush language.

Therefore, in view of Applicants' claim amendments, Applicants submit that Claims 1-9 are no longer indefinite. Applicants, therefore, respectfully request that this rejection be withdrawn.

***Rejection of Claims 1 - 9 under 35 USC §103(a) - Lai***

Claims 1 - 9 stand rejected under 35 USC §103(a) as being obvious under US Patent No. 5,449,729 to *Lai*.

The present invention is concerned with a novel prepolymer which is obtained by (a) **telomerizing a hydrophilic monomer**, for example DMA, and a **crosslinker**, e.g., a difunctional polysiloxane, in the presence of a **functional chain transfer agent**, for example cysteamine hydrochloride, and (b) endcapping the resulting polymer, in particular functional groups of the incorporated chain transfer agent, with a compound comprising an ethylenically unsaturated double bond.

In strong contradiction thereto, *Lai* '729 is totally silent about a telomerization reaction in the presence of a chain transfer agent. The reference is solely concerned with the thermally or photochemically induced polymerization of one or more hydrophilic monomers in the presence of a crosslinker which is known in the art.

In addition, the novel prepolymers and the underlying manufacturing process are a breakthrough in the field of biomedical polymers. Specifically, the telomerization of **mono**-ethylenically unsaturated compounds or mixtures of **mono**-ethylenically unsaturated compounds in the presence of a chain transfer agent is known. In the past, telomers were specifically tailored to products with a specific chain lengths and a small distribution of molecular weights. However, nobody in the biomedical art ever before contemplated to add a crosslinker, that is a compound having two or more C-C double bonds, in such a telomerization reaction, because this would have been contradictory to the aim of the telomerization reaction. The addition of a crosslinker in such a telomerization reaction would have been expected to create chaos, i.e., a gelling of the reaction mixture, or the like, instead of yielding tailored telomers.

It is the surprising and unexpected finding of the claimed invention that by simple choice of suitable amounts of monomer, crosslinker, and chain transfer agent, valuable prepolymers may be designed using said telomerization reaction, which upon

crosslinking yield biomedically acceptable polymers with a wide range of valuable properties. For example, upon reacting a hydrophilic monomer and a hydrophobic crosslinker (polysiloxane) in the presence of a chain transfer agent, biomedical articles may be obtained after crosslinking, which are specifically tailored, for example with respect to ion permeability, oxygen permeability, and/or mechanical stability (modulus) just by subtle variation of the ingredients making up the polymer.

Lai is completely silent about this reaction technique, and therefore, does not suggest the presently claimed invention.

Therefore, since the cited combination of prior art does not fairly teach or suggest the claimed invention, Claims 1 - 9 are not rendered obvious by *Lai*. Applicants, therefore, respectfully request that this rejection be withdrawn.

***Rejection of Claims 1 - 3 and 7 - 9 under 35 USC §102/§103 - Jung***

Claims 1 - 3 and 7 - 9 stand rejected under 35 USC §102/§103 as being anticipated by, or in the alternative, obvious under US Patent No. 5,227,432 to *Jung*.

Applicants have amended Claim 1 to incorporate the limitations of Claim 4. Applicants respectfully submit that Jung does not fairly teach or suggest such a crosslinker.

Therefore, since the cited prior art does not fairly teach or suggest the claimed invention, Claims 1 - 3 and 7 - 9 are not anticipated or rendered obvious by *Jung*. Applicants, therefore, respectfully request that this rejection be withdrawn.

**CONCLUSION**

In view of the foregoing and in conclusion, Applicants submit that the 35 USC §§102, 103, and 112 rejections set-forth in the Office Action have been overcome, and that the pending claims are not indefinite, anticipated by, or obvious over the cited art, either individually or in combination. Applicants request reconsideration and withdrawal of the rejection(s) set-forth in the Office Action. Should the Examiner believe that a discussion with Applicants' representative would further the prosecution of this application, the Examiner is respectfully invited to contact the undersigned.

Application No.: 09/815,674

Please address all correspondence to Novartis Corporation, Corporate Intellectual Property, One Health Plaza, Bldg. 430, East Hanover, NJ 07936-1080. The commissioner is hereby authorized to charge any other fees which may be required under 37 C.F.R. §1.16 and 1.17, or credit any overpayment, to Deposit Account No. 19-0134.

Respectfully submitted,



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**VERSION WITH MARKING TO SHOW CHANGES MADE**

***In the Specification***

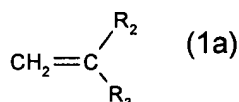
Please amend the specification as follows:

***In the Claims***

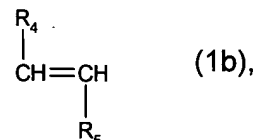
Please delete Claim 4.

Please amend Claims 1 - 3 as follows:

1. (amended) A crosslinkable or polymerizable prepolymer that is obtainable ~~obtained~~ by
- (a) copolymerizing at least one hydrophilic monomer having one ethylenically unsaturated double bond and at least one crosslinker comprising two or more ethylenically unsaturated double bonds in the presence of a chain transfer agent having a functional group; and
- (b) reacting one or more functional groups of the chain transfer agent ~~comprised in the~~ resulting copolymer with an organic compound having an ethylenically unsaturated group;
- wherein the crosslinker according to step (a) is a polysiloxane, perfluoroalkyl polyether or polysiloxane/perfluoroalkyl polyether block copolymer comprising in each case two or more ethylenically unsaturated double bonds;
- wherein the hydrophilic monomer is a monomer which gives, as a homopolymer, a polymer which is water-soluble or can absorb at least 10% by weight of water.
2. (amended) A prepolymer according to claim 1, wherein the hydrophilic monomer according to step (a) is a radical of formula



or



wherein R<sub>2</sub> is hydrogen or C<sub>1</sub>-C<sub>4</sub>-alkyl;

R<sub>4</sub> is C<sub>1</sub>-C<sub>4</sub>-alkyl, phenyl or a radical -C(O)OY<sub>9</sub>, wherein Y<sub>9</sub> is hydrogen or unsubstituted or hydroxy-substituted C<sub>1</sub>-C<sub>4</sub>-alkyl;

R<sub>5</sub> is a radical -C(O)Y<sub>9</sub>' or -CH<sub>2</sub>-C(O)OY<sub>9</sub>' wherein Y<sub>9</sub>' independently has the meaning of Y<sub>9i</sub>; and

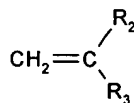
R<sub>3</sub> is

- (i) a non-ionic substituent selected from the group consisting of C<sub>1</sub>-C<sub>6</sub>-alkyl which is substituted by one or more same or different substituents selected from the group consisting of -OH, C<sub>1</sub>-C<sub>4</sub>-alkoxy and -NRR', (wherein R and R' are each independently of another hydrogen or unsubstituted or hydroxy-substituted C<sub>1</sub>-C<sub>6</sub>-alkyl or phenyl, <sup>(2)</sup>phenyl which is substituted by hydroxy, C<sub>1</sub>-C<sub>4</sub>-alkoxy or -NRR', wherein R and R' are as defined above; a radical -COOY, wherein Y is C<sub>1</sub>-C<sub>4</sub>-alkyl, C<sub>1</sub>-C<sub>24</sub>-alkyl which is substituted by hydroxy, C<sub>1</sub>-C<sub>4</sub>-alkoxy, -O-Si(CH<sub>3</sub>)<sub>3</sub>, -NRR' wherein R and R' are as defined above, a radical -O-(CH<sub>2</sub>CH<sub>2</sub>O)<sub>1-24</sub>-E wherein E is hydrogen or C<sub>1</sub>-C<sub>6</sub>-alkyl, or a radical -NH-C(O)-O-G, wherein -O-G is the radical of a saccharide with 1 to 8 sugar units or is a radical -O-(CH<sub>2</sub>CH<sub>2</sub>O)<sub>1-24</sub>-E, wherein E is as defined above, or Y is C<sub>5</sub>-C<sub>8</sub>-cycloalkyl which is unsubstituted or substituted by C<sub>1</sub>-C<sub>4</sub>-alkyl or C<sub>1</sub>-C<sub>4</sub>-alkoxy, or is unsubstituted or C<sub>1</sub>-C<sub>4</sub>-alkyl- or C<sub>1</sub>-C<sub>4</sub>-alkoxy-substituted phenyl or C<sub>7</sub>-C<sub>12</sub>-aralkyl, <sup>(1)</sup>CONY<sub>1</sub>Y<sub>2</sub> wherein Y<sub>1</sub> and Y<sub>2</sub> are each independently

hydrogen, C<sub>1</sub>-C<sub>4</sub>-alkyl, C<sub>1</sub>-C<sub>12</sub>-alkyl, which is substituted by hydroxy, C<sub>1</sub>-C<sub>4</sub>-alkoxy, a radical -CH(OR<sub>18</sub>)<sub>2</sub> wherein R<sub>18</sub> is hydrogen, C<sub>1</sub>-C<sub>4</sub>-alkyl or C<sub>2</sub>-C<sub>5</sub>-alkanoyl, or a radical -O-(CH<sub>2</sub>CH<sub>2</sub>O)<sub>1-24</sub>-E wherein E is as defined above, or Y<sub>1</sub> and Y<sub>2</sub> together with the adjacent N-atom form a five- or six-membered heterocyclic ring having no additional heteroatom or one additional oxygen or nitrogen atom; a radical -OY<sub>3</sub>, wherein Y<sub>3</sub> is hydrogen, C<sub>1</sub>-C<sub>4</sub>-alkyl or C<sub>1</sub>-C<sub>12</sub>-alkyl which is substituted by -NRR', or is a radical -C(O)-C<sub>1</sub>-C<sub>4</sub>-alkyl; and wherein R and R' are as defined above; or a five- to seven-membered heterocyclic radical having at least one N-atom and being bound in each case via said nitrogen atom; or

- (ii) an anionic substituent selected from the group consisting of C<sub>1</sub>-C<sub>6</sub>-alkyl which is substituted by -SO<sub>3</sub>H, -OSO<sub>3</sub>H, -OPO<sub>3</sub>H<sub>2</sub> and -COOH; phenyl which is substituted by one or more same or different substituents selected from the group consisting of -SO<sub>3</sub>H, -COOH, -OH and -CH<sub>2</sub>-SO<sub>3</sub>H; -COOH; a radical -COOY<sub>4</sub>, wherein Y<sub>4</sub> is C<sub>1</sub>-C<sub>24</sub>-alkyl which is substituted by -COOH, -SO<sub>3</sub>H, -OSO<sub>3</sub>H, -OPO<sub>3</sub>H<sub>2</sub> or by a radical -NH-C(O)-O-G' wherein G' is the radical of an anionic carbohydrate; a radical -CONY<sub>5</sub>Y<sub>6</sub> wherein Y<sub>5</sub> is C<sub>1</sub>-C<sub>24</sub>-alkyl which is substituted by -COOH, -SO<sub>3</sub>H, -OSO<sub>3</sub>H, or -OPO<sub>3</sub>H<sub>2</sub> and Y<sub>6</sub> independently has the meaning of Y<sub>5</sub> or is hydrogen or C<sub>1</sub>-C<sub>12</sub>-alkyl; or -SO<sub>3</sub>H; or a salt thereof; or
- (iii) a cationic substituent selected from the group consisting of C<sub>1</sub>-C<sub>12</sub>-alkyl which is substituted by a radical -NRR'R''<sup>+</sup>An<sup>-</sup>, wherein R, R' and R'' are each independently of another hydrogen or unsubstituted or hydroxy-substituted C<sub>1</sub>-C<sub>6</sub>-alkyl or phenyl, and An<sup>-</sup> is an anion or a radical -C(O)OY<sub>7</sub>, wherein Y<sub>7</sub> is C<sub>1</sub>-C<sub>24</sub>-alkyl which is substituted by -NRR'R''<sup>+</sup>An<sup>-</sup> and is further unsubstituted or substituted by hydroxy, wherein R, R', R'' and An<sup>-</sup> are as defined above; or
- (iv) a zwitterionic substituent -R<sub>1</sub>-Zw, wherein R<sub>1</sub> is a direct bond or a carbonyl, carbonate, amide, ester, dicarboanhydride, dicarboimide, urea or urethane group; and Zw is an aliphatic moiety comprising one anionic and one cationic group each.

3. (amended) A prepolymer according to claim 1, wherein the hydrophilic monomer according to step (a) is a radical of formula



(1a)

wherein R<sub>2</sub> is hydrogen or methyl and R<sub>3</sub> is a non-ionic substituent selected from the group consisting of -COO-C<sub>1</sub>-C<sub>2</sub>-alkyl, -COO-(CH<sub>2</sub>)<sub>2-4</sub>-OH, -CONH<sub>2</sub>, -CON(CH<sub>3</sub>)<sub>2</sub>,

-CONH-(CH<sub>2</sub>)<sub>2</sub>-OH, -CONH-(CH<sub>2</sub>)<sub>1-3</sub>-CH(OC<sub>1</sub>-C<sub>2</sub>-alkyl),  $\begin{array}{c} \text{O} \\ \parallel \\ \text{---C---N---} \end{array} \begin{array}{l} \text{C}_1\text{-C}_2\text{-alkyl} \\ \text{CH}_2\text{CH}_2\text{-OH} \end{array}$ ,

